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## What is the California Institute for Regenerative Medicine (CIRM)?

CIRM, California's stem cell institute, was created by the voters of California in 2004 when they overwhelmingly passed Proposition 71, which authorized \$3 billion in funding for stem cell research in California. The institute funds stem cell research at institutions and companies throughout California (as well as institutions and companies outside of the state that conduct a portion of their research in California) with the goal of accelerating treatments to patients with unmet medical needs. Here is the text of Proposition 71.

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### What does the stem cell institute do?

CIRM uses money from bond sales to accelerate the pace of stem cell research in California. CIRM doesn't carry out research itself. Instead, it solicits research proposals and funds research, training and new facilities throughout the state. A list of all our funded awards is available here.

The ultimate goal of our programs is to fast-track stem cell treatments to patients with unmet medical needs. By promoting and encouraging the growth of the stem cell biotechnology sector, the institute is also helping attract the best scientists to the state and establishing California as a global leader in stem cell research.

### Find Out More:

Stem Cell Basics

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### What has CIRM funded?

The vast majority of our funds go to advance research and the development of new treatments. In support of this goal, we have helped fund the building of much-needed scientific facilities, created innovative initiatives such as the Alpha Stem Cell Clinics Network, and developed educational programs that train future stem cell scientists.

When we were created in 2004, there were few facilities in California where scientists could work with all types of stem cells, particularly embryonic stem cells, and few scientists had access to labs that contained all the equipment needed to do this specialized work. One of our earliest rounds of funding went to build lab spaces that could be shared by researchers within the institution and also used to train younger scientists on how to work with stem cells.

Training was (and is) needed to build the field and create the next generation of stem cell scientists. New therapies won't happen without people trained to work with stem cells who have both the technical skills and the equipment they need. We have funded programs to train high school students, college students, graduate students and early career scientists. For more about the different educational programs we've funded, visit our Training Tomorrow's Scientists Page.

Most of our funding goes to the research itself. In the early years, because this was such a new field, much of the funding was focused on fundamental, basic science, to help develop a deeper understanding of stem cells and how they worked. More recently we have begun to move the most promising ideas that came out of that earlier funding into clinical trials where they can be tested in people. We've also established the Alpha Stem Cell Clinics Network, which conducts high quality stem cell trials for a wide variety of diseases at leading medical centers in California.

#### **Find Out More:**

How our funds have been allocated.

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#### Does CIRM fund clinical trials?

Yes. In our first ten years, we funded ten projects that were approved to run clinical trials including work in heart disease, cancer, HIV/AIDS, two different forms of blindness and sickle cell disease, to name a few. We also funded the early research in nine other projects that led to clinical trials. To learn about the latest list of clinical trials that CIRM is funding, visit our Funding Clinical Trials page.

Now our goal is to dramatically increase that number and to fund 50 new clinical trials by 2021. You can read more about this goal in our Strategic Plan and read about our progress in our recent Annual Reports.

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## Why did CIRM fund new buildings?

When California's stem cell institute started in 2004, little research space existed where scientists could work with all types of stem cells, particularly embryonic stem cells, and that contained the equipment needed to work with the cells and – most importantly – develop new therapies. Stem cell scientists were also spread thinly across many research campuses, limiting interactions and slowing the spread of ideas. One of the greatest needs therefore was laboratory space for these scientists to work and collaborate.

The institute provided \$271 million toward 12 buildings throughout the state, requiring the institutions to contribute the remaining \$543 million to construct and furnish the buildings. That money largely came from donations from individuals or foundations that were inspired by the institute's initial commitment to contribute toward the project. This public/private partnership created much-needed work for the construction industry and new, full-time jobs for researchers and other staff.

### Find Out More:

CIRM-funded facilities and the major donors to each.

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### Has CIRM made any money for the state?

The institute's grants create jobs in California and have expanded the biotechnology industry – propelling California as a world leader in stem cell research. Our grants for new buildings also created construction jobs at a time when the state desperately needed them.

An independent analysis found that by the end of 2014, the institute's major facilities program alone created 38,000 job-years (this is economist-speak for creating the equivalent of 38,000 jobs that last one year, or 19,000 jobs that last two years) and brought in \$286 million in new tax revenue. Our other programs create research positions, and positions associated with the fast-growing biotech industry here in California.

You can read the independent economic impact report about CIRM here.

The tax revenue that results from the institute's funding goes directly into the state's general fund, where it pays for the interest on our bonds as well as other programs in the state.

As our funding begins to lead to the development of new therapies, a portion of the profits from the sale of those therapies will also be returned to the state. And of course because these therapies are treating diseases that currently have no effective remedy we will also be reducing the health care burden on California, reducing medical spending and improving the quality of life for people in the state.

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## What diseases are you working on?

There are a wide variety of diseases that CIRM-funded scientists are working on, including those that pose the greatest threat to Americans. These include heart disease, stroke, cancer, diabetes, Alzheimer's and Parkinson's disease, among others. We are also working on diseases that affect far fewer people but are no less deadly and which are largely untreatable, such as Huntington's disease, sickle cell disease, autism, muscular dystrophy and Lou Gehrig's disease (ALS).

#### Find Out More:

Disease pages for more about how stem cell treatments stand to benefit diseases. All CIRM awards that you can filter by disease area.

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### When will there be cures?

The path from a scientific discovery to a new cure is on the order of decades or longer – although sometimes discoveries can move quickly to the clinic. For example, James Thompson and his team first generated human embryonic stem cells in 1998 and the first trial based on those cells started in 2010 – a remarkably fast timeline for new therapies. The reprogrammed induced pluripotent (iPS) cells that earned Shinya Yamanaka a Nobel Prize in 2012 were only discovered in 2007, and by 2014, were already being tested in a first-in-human clinical trial.

Since the launch of our Strategic Plan, we've attempted to dramatically speed up the pace of research and accelerate the development of stem cell treatments for patients with unmet medical needs. For clinical stage projects, for example, instead of having a single round of funding with one application deadline every, say, 12 months, we now have an open application program with deadlines every month. And instead of taking 22 months to move from application to funding that now takes just 120 days.

We have also overhauled the way we fund Discovery (or basic) and Translation research, making these funding opportunities available on a more regular basis and in a more targeted fashion. Our goal is to create a research pipeline for the most promising projects, moving from Discovery to Translation and into Clinical in the shortest time possible.

To support this work, we are creating two new centers, an Accelerating and a Translating Center, to help researchers speed up the pace of their clinical research and shorten the time it takes to get approval to test these therapies in patients. We've also created the CIRM Alpha Stem Cell Clinics Network, a series of highly specialized medical centers that have the skills, experience and expertise needed to offer stem cell therapies to patients.

But research is only part of the equation when it comes to developing cures. We are also working with the US Food and Drug Administration (FDA), which regulates clinical trials, to try and speed up the regulatory process. We want to remove unnecessary obstacles to create a process that is easier and faster, but no less safe, in moving the most promising research out of the lab and into people. You can find out how you can help us do this by going to our Stem Cells Champion page.

### **Find Out More:**

How we are smoothing the path to new therapies CIRM Stem Cell Champions page

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### Proposition 71 gave you \$3 billion over ten years. What happens when the money runs out?

Right now we are exploring a number of different options to try and ensure that we are able to continue funding stem cell research after the money allocated to us by Proposition 71 runs out. Those include raising funds from philanthropic sources and partnering with industry to enable us to continue our mission.

SB1064 required CIRM to create a transition plan for when our funds run out.

#### Find Out More:

CIRM Transition Plan

## What organizations are eligible to receive funding?

Funding is open, as it always has been, to both companies and academic institutions.

Applicants do not have to be in California to apply, however, they will have to have some California connection to be eligible for funding. To qualify as a California organization, they must have more than 50% of their employees located in the state, and they must conduct the activities covered by the award in California (with some limited exceptions).

#### **Find Out More:**

All organizations that have received CIRM funding. All stem cell grants awarded by CIRM. List of CIRM collaborative partnerships.

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### Can the funding be used to fund research on human reproductive cloning?

No. Reproductive cloning is specifically prohibited under Proposition 71 and under California law.

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## Does stem cell research harm human embryos?

Almost all human embryonic stem cell lines come from embryos left over from in vitro fertilization (IVF). These embryos are only about four to five days old and contain roughly 100 cells. This stage is called the blastocyst, which at this point is smaller than the size of the dot over an "i." The hollow blastocyst – which is where embryonic stem cells come from – contains a cluster of 20-30 cells called the *inner cell mass*. These are the cells that become embryonic stem cells in a lab dish. The process of extracting these cells destroys the embryo.

All the embryos used in CIRM-funded research were *donated* from IVF clinics. They had either been rejected for implantation and were going to be destroyed, or the couple had decided to stop storing the embryos for future use. The embryos used to create embryonic stem cell lines *were already destined to be destroyed*.

There is, however, a second method that creates embryonic stem cell lines without destroying the embryo. Instead, scientists take a single cell from a very early stage IVF embryo and can use that one cell to develop a new line. The process of removing one cell from an early stage embryo has been done for many years as a way of testing the embryo for genetic predisposition to diseases such as Tay Sachs. This process is called *preimplantation genetic testing*.

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# Why are we paying for stem cell research, shouldn't that be a job for private industry?

State and national governments have a long history of being involved in the kind of pioneering research that private industry is unable or unwilling to do. Private industry has to focus on the financial return, making them unlikely to fund high-risk projects. Government agencies can fund research with a focus on benefits to the public rather than on making money.

At the Federal level, the government's support was vital to the success of the Human Genome Project, and funding from the NIH led to the development of 15 of the top 21 drugs introduced between 1965 and 1992.

Private industry tends to focus on projects that are in later stages of development. Without funding for the earliest stages of discovery, there will be no stem cell therapies making it into those later stages where private industry becomes involved.

Scientists have referred to the stage right before industry becomes interested as the "Valley of Death". It's an area where promising therapies often languish, because there isn't enough federal funding to push the projects through to the later stages. CIRM has focused on funding the early research that leads to therapy ideas, and we fund projects that are in the Valley of Death stage, helping to keep good projects on track toward the clinic. We also fund later stages that verify promising therapies and begin clinical trials in people.

#### **Find Out More:**

The Therapy Development Pipeline

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#### Doesn't the NIH fund stem cell research?

The NIH and other federal agencies do fund stem cell research and do play a vital role in driving scientific discovery. However, they have very broad research interests. With CIRM's focus on stem cell research, we are able to work closely with academics and industry to craft our funding programs in a way that accelerates the field. Our programs are timed so that researchers with successful projects will have continuous funding from the basic laboratory research through to clinical trials. The NIH tends to focus more heavily on early stage research, forcing scientists with promising ideas to pause their research and look for new sources of funding as the projects get closer to clinical trials.

CIRM also works closely with our research team partners to help them navigate regulations leading up to clinical trials, and to find industry partners to help fund the later stage research. This ability to focus on accelerating stem cell research toward clinical trials is only possible for an institute with CIRM's mission.

The NIH is also restricted in the types of research it can fund. Unlike the NIH, CIRM funds the creation of new stem cell lines, lines that have been critical to the success of some research programs.

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## How can I stay up to date about CIRM's activities?

We have several ways of keeping people up to date on our research progress.

- Sign up for our email lists. We have four different lists that provide people with information about CIRM news, new funding
  opportunities, and opportunities to attend public meetings.
- Read our blog, The Stem Cellar. We report on progress by CIRM grantees and update readers on the field of stem cell research.
- Follow us on social media. We have active Facebook, Twitter, YouTube and Flickr channels

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# Can I donate to CIRM?

Under Proposition 71, CIRM can accept donations of "additional revenue and real and personal property [including cash], including, but not limited to gifts, royalties, interest, and appropriations that may be used to supplement annual research grant funding and the operations of the institute." To implement this section, our governing board has adopted a policy and procedure on the acceptance of donated real and personal property.

#### Find Out More:

CIRM Gift Policy [pdf]

Is your question not answered here? Please contact CIRM directly.

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